

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0522]

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Certifier A. Corbin

**Draft Guidance for Industry and Food and Drug Administration Staff;
Premarket Submissions and Labeling Recommendations for Drugs of Abuse
Screening Tests; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Draft Guidance for Industry and FDA Staff; Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests." This draft guidance is intended to assist industry in preparing premarket notification submissions for drugs of abuse screening tests. The draft guidance also provides recommendations regarding the labeling of these tests. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff; Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send

two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jean Cooper, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301-594-1243

SUPPLEMENTARY INFORMATION:

I. Background

On November 14, 2000, FDA issued two draft guidance documents entitled “Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications” and “Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications” (docket nos. 1999D-1020 and 2000D-1587). This draft guidance replaces those documents and is intended to address concerns about those documents, including concerns regarding a recommendation that the cost of confirmatory testing be bundled with the cost of screening tests. Among other changes, the draft guidance FDA is issuing today recognizes that measures other than bundling the cost of confirmatory testing may help mitigate the risk of inaccurate results. The new draft guidance also clarifies that premarket submissions for drugs of abuse screening tests used in workplace and other repetitive testing sites may not require the same types of data as submissions for screening tests that are intended for sale

directly to untrained users. The draft guidance is intended to assist manufacturers in preparing premarket submissions for drugs of abuse tests used in any setting, including hospital, workplace, sports, insurance, and home settings. The draft guidance also provides recommendations on labeling drugs of abuse screening tests.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on premarket submissions and labeling of drugs of abuse screening tests. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Draft Guidance for Industry and FDA Staff; Premarket Submissions and Labeling Recommendations for Drugs of Abuse Screening Tests" by fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (152) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved

applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

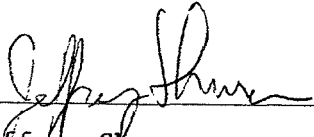
IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E) (OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document at any time. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/13/03
November 13, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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